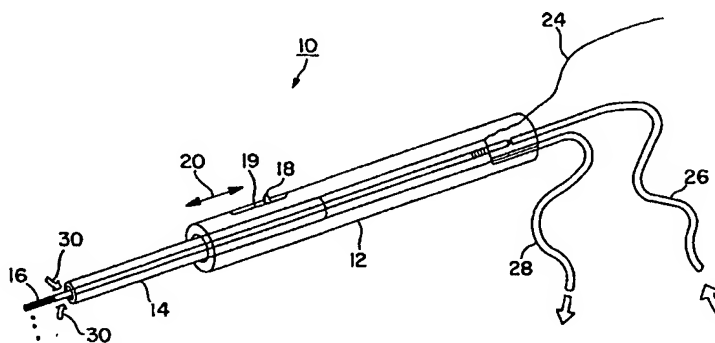




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 18/14, A61M 1/00	A1	(11) International Publication Number: WO 98/14131 (43) International Publication Date: 9 April 1998 (09.04.98)
(21) International Application Number: PCT/US96/15796 (22) International Filing Date: 2 October 1996 (02.10.96) (71) Applicant: MEDTRONIC, INC. [US/US]; 7000 Central Avenue Northeast, Minneapolis, MN 55432 (US). (72) Inventors: MULIER, Peter, M., J.; 1408 Forest Lane, St. Paul, MN 55112 (US). HOEY, Michael, F.; 5377 Pond Drive, Shorview, MN 55126 (US). (74) Agents: KINGHORN, Curtis, D. et al.; Medtronic, Inc., 7000 Central Avenue Northeast, MS301, Minneapolis, MN 55432 (US).		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>

(54) Title: FLUID-ASSISTED ELECTROCAUTERY DEVICE



(57) Abstract

An electrocautery instrument (10) is provided with a source of conductive fluid coupled to a proximal end of a hollow electrode (16). Conductive fluid is communicated through said electrode (16) and expelled out of the distal end thereof during electrocautery, forming a "virtual electrode". The infused conductive liquid conducts the RF electrocautery energy away from the conductive electrode (16), thereby displacing the region of thermal generation and reducing the extent of burns and perforations caused by conventional electrocautery electrodes. In one embodiment, the electrode (16) is partially disposed within and extends distally out of a retractable suction tube (14), such that smoke and fluid are aspirated from the electrocautery site. When the suction tube (14) is fully advanced, the electrode (16) is concealed therein, enabling suction without electrocautery to be performed.

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FLUID-ASSISTED ELECTROCAUTERY DEVICE**FIELD OF THE INVENTION**

This invention relates generally to the field of medical instruments, and more particularly relates to an electrocautery device.

BACKGROUND OF THE INVENTION

Various types of electrocautery devices for incising and cauterizing body tissue are known and used in the medical field. Typically, such devices include a conductive blade or needle which serves as one electrode in an electrical circuit which is completed via a grounding electrode coupled to the patient. Incision of tissue is accomplished by applying a source of electrical energy (most commonly, a radio-frequency generator) to the blade. Upon application of the blade to the tissue, a voltage gradient is created, thereby inducing current flow and related heat generation at the point of contact. With sufficiently high levels of electrical energy, the heat generated is sufficient to cut the tissue and, advantageously to simultaneously cauterize severed blood vessels.

It is widely recognized in the prior art that the often substantial amount of smoke produced by electrocauterization of tissue is at least unpleasant, and in some cases distracting or even hazardous to the operator and other attending medical personnel. As a result, it has been proposed, and is common, to provide an electrocautery device with smoke-aspirating capabilities, such that the smoke produced from electrocauterization is quickly withdrawn from the area of incision. Smoke aspiration may be accomplished by providing, in the handle of the electrocautery device near the electrocautery blade/electrode, an inlet port to be coupled to a vacuum or suction source. Examples of this are described in U.S. Patent No. 4,307,720 to Weber, Jr., entitled "Electrocautery

Apparatus and Method and Means for Cleaning the Same;" in U.S. Patent No. 5,242,442 to Hirschfeld, entitled "Smoke Aspirating Electrosurgical Device;" and in U.S. Patent No. 5,269,781 to Hewell, entitled "Suction Assisted Electrocautery Unit."

It has also been recognized in the prior art that the accumulation of coagulated blood, tissue rubble, and other debris on the electrode/blade of an electrocautery device can present a problem for the operator, necessitating the periodic cleaning of the blade, e.g., by wiping the blade over sterilized gauze or the like. This is generally regarded as undesirable, since the need to clean the electrode/blade tends to interrupt the incision procedure and increases the risks associated with contamination of the blade or the incision, damage to the blade, injury to the operator, and the like. To address this problem, it has been proposed in the prior art to provide an electrocautery instrument in which the electrode/blade is in slidable engagement with the instrument's handle, such that when the blade is retracted into the hand, any adhering debris automatically scraped off onto the tip of the handle. Such an instrument is proposed in the above-referenced Weber, Jr. '720 patent. While this arrangement may have some benefit, it still may be necessary to wipe off the tip of the handle once the blade is retracted. It is believed that a more direct and effective approach to the problem would be to reduce the amount of debris created during the electrocautery process, thereby eliminating or at least reducing the need to clean the electrode/blade.

SUMMARY OF THE INVENTION

In view of the foregoing considerations, the present invention is directed to an improved electrocautery instrument.

In one embodiment of the invention, an electrocautery instrument is configured with an electrode/blade disposed within a retractable suction tube, such that with the suction tube advanced, the electrode/blade is concealed within the tube, and with the suction tube retracted, the distal end of the electrode/blade is exposed for performing electrocautery.

In accordance with one aspect of the invention, the electrocautery electrode/blade is implemented with a hollow, conductive tube, flattened at its distal end into a blade-like configuration. Conductive fluid is applied to the proximal end of the hollow electrode/blade, and expelled from the distal (blade) end thereof during electrocautery. In accordance with another aspect of the invention, the conductive fluid emanating from the electrode/blade conducts the RF electrocautery energy away from the blade, so that it is primarily the fluid, rather than the metal blade, which actually accomplishes the cutting of tissue. That is, the fluid serves as a "virtual" electrocautery electrode. Since it is the fluid, rather than the blade, which incises and cauterizes, no burns or perforations are made to the tissue, reducing the amount of debris in the incision. Also, the flow of fluid through the electrode/blade tends to keep the blade clean and cool.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other aspects of the present invention may perhaps be best appreciated with reference to a detailed description of a specific embodiment of the invention, when read in conjunction with the accompanying drawings, wherein:

Figure 1 is a perspective view of an electrocautery instrument in accordance with one embodiment of the invention; and

Figure 2 is a enlarged perspective view of the distal end of the electrode/blade of the electrocautery instrument of Figure 1.

DETAILED DESCRIPTION OF A SPECIFIC EMBODIMENT OF THE
INVENTION

5 Referring to Figure 1, there is shown a perspective view of a fluid-assisted electrocautery instrument 10 in accordance with one embodiment of the invention. Electrocautery instrument 10 comprises a handle 12, a suction tube 14, and an electrocautery electrode/blade 16. Handle 12 is preferably made of a sterilizable, rigid, and non-conductive material, such as nylon or the like. Suction tube 14, which is also
10 preferably made of a sterilizable and non-conductive material, is slidably disposed partially within an internal lumen of handle 12, and projects distally out of the end thereof. Electrode/blade 16 is disposed within suction tube 14 and handle 12. Suction tube 18 is adapted to slide proximally and distally with respect to handle 12 and electrode 16 (i.e., in the directions of arrow 20 in Figure 1) by means of a sliding lever
15 18 extending out of a slot 19 in handle 12. With suction tube 14 in a retracted position, as shown in Figure 1, a distal portion of electrode/blade 16 projects beyond the distal end of tube 14, such that electrocautery can be performed. With suction tube in an advanced position, suction tube 14 completely conceals the tip of electrode/blade 16.

In accordance with one aspect of the invention, electrode/blade 16 is preferably
20 implemented using a hollow cylindrical tube which has been flattened at its distal end, as shown in the greatly enlarged perspective view of Figure 2. In addition to being flattened, a portion of the distal end of electrode/blade 16 is removed to form a longitudinal slit 22 therein.

Three connections are made to electrocautery instrument 10: One terminal (e.g., positive) of a radio-frequency (RF) generator (not shown in Figure 1) is electrically coupled to electrode/blade 16 via a wire 24; a source of fluid to be expelled from slit 22 in electrode/blade 16 is coupled to the proximal end of electrode/blade 16 via a flexible tube or hose 26; and a suction hose 28 is coupled to handle 12 so as to be in communication with the internal lumen of handle 12 and with suction tube 14. When suction is applied via hose 28, air and fluid are drawn into the distal end of suction tube 14, as indicated by arrows 30. The ability to advance or retract suction tube 14 with respect to electrode/blade 16 enables the operator of the instrument to perform electrocautery while simultaneously aspirating smoke and fluid from the incision site, or to use suction tube 14 alone, without performing electrocautery.

As noted above, conductive fluid is communicated from inflow tube 26 and communicated along the length of electrode/blade 16 to be expelled from the distal end thereof. This is done in order to establish a so-called virtual electrode for performing electrocautery. The infusion of conductive fluid simultaneously with the application of RF energy is discussed in further detail in: U.S. patent application serial number 08/113,441 entitled "Method and Apparatus for R-F Ablation," filed on August 27, 1993 in the name of Peter M.J. Mulier and Michael F. Hoey, in U.S. patent application serial number 08/303,246, entitled "Method and Apparatus for RF Ablation," filed on September 8, 1994 in the name of Peter M.J. Mulier; and in U.S. patent application S.N. 08/302,304 entitled "Method and Apparatus for RF Ablation," filed in the name of Peter M.J. Mulier and Michael F. Hoey on September 8, 1994. The foregoing '441 '246, and '304 applications (hereinafter collectively referred to as "the RF ablation

applications”) are each commonly assigned to the assignee of the present invention, and incorporated by reference herein in their respective entireties.

As described in the RF ablation patents, the infusion of conducting fluid into the area of application of RF energy creates a “virtual electrode,” the size and shape of which can be controllably modified, and which can be rendered more or less
5 conductive, thereby modifying the spread of RF energy. By varying such factors as the RF energy and duration, the rate of infusion of conductive liquid, and the conductivity of the infused solution, the size, shape, and intensity of the “virtual electrode” -- i.e., the intensity of thermal production in the area, can be controlled. In the case of the
10 electrocautery device in accordance with the present invention, application of the conductive solution during the application of RF energy further assists by preventing overheating of the electrode/blade, extending the point at which burning or charring of tissue would otherwise normally occur. To enhance this effect, it is contemplated that the solution being infused may first be cooled.

15 Conductive solutions believed to be suitable for establishing the virtual electrode include saline, saturated saline, and Ringer’s solution, among others. Regarding the source of conductive fluid, it is contemplated that a conventional pump may be coupled to input line 26. Alternatively, it is contemplated that a small, pre-pressurized canister of conductive solution may be used, such that no pump is required. In one
20 embodiment, handle 12 may be configured to receive such a pressurized canister therein, eliminating the need for input line 26.

Although in the embodiment of Figure 1, input line 26, suction line 28, and electrical connection 24 are depicted separately, it is contemplated that these connections

to instrument 10 may be consolidated into a single line having two separate fluid-conducting lumens therein (one for input of conductive solution, one for suction), alongside an insulated electrical conductor.

5 Various alternate configurations of electrode/blade 16 are also contemplated. In one embodiment, a porous metal element is substituted for the flattened tube configuration of Figures 1 and 2.

10 From the foregoing detailed description of a specific embodiment of the invention, it should be apparent that a method and apparatus for performing fluid-assisted electrocautery of body tissue has been disclosed, wherein fluid delivered out of a hollow electrocautery electrode/blade creates a virtual electrode which incises and cauterizes the tissue.

15 Although a specific embodiment of the invention has been described herein, this has been done solely for the purposes of illustrating various aspects of the invention, and is not intended to be limiting with respect to the scope of the invention. It is contemplated that various substitutions, alterations, and/or modifications, including but not limited to those specifically discussed herein, may be made to the disclosed embodiment without departing from the spirit and scope of the invention as defined in the appended claims, which follow.

WHAT IS CLAIMED IS:

1. A fluid-assisted electrocautery instrument, comprising:
an elongate handle having proximal and distal ends and having a longitudinal lumen extending between said proximal and distal ends;
5 a suction tube, disposed partially within said lumen of said handle and having a distal end extending out of said distal end of said handle;
a conductive electrocautery electrode adapted to be coupled to a source of radio-frequency energy, said electrode comprising an elongate tube defining an internal lumen extending between proximal and distal ends of said electrode, said electrode disposed
10 within said suction tube such that a distal end of said electrode extends distally beyond said distal end of suction tube;
a fluid input tube, coupled to said proximal end of said electrode and in fluid communication with said internal lumen of said electrode, such that conductive fluid supplied from said input tube is communicated along said electrode and expelled from
15 said distal end of said electrode.
2. An electrocautery instrument in accordance with claim 1, wherein said distal end of said electrode is flattened into a blade-like configuration.
3. An electrocautery instrument in accordance with claim 1, further comprising: a suction hose, adapted to be coupled between said proximal end of said
20 suction tube and a suction pump, for aspirating smoke and fluid during electrocautery.
4. An electrocautery instrument in accordance with claim 1, wherein said suction tube is slidably disposed in said handle such that said suction tube is

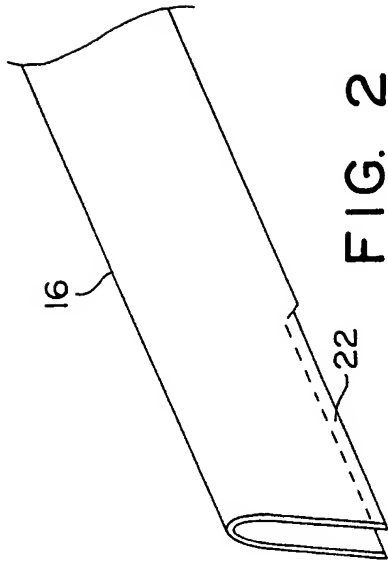
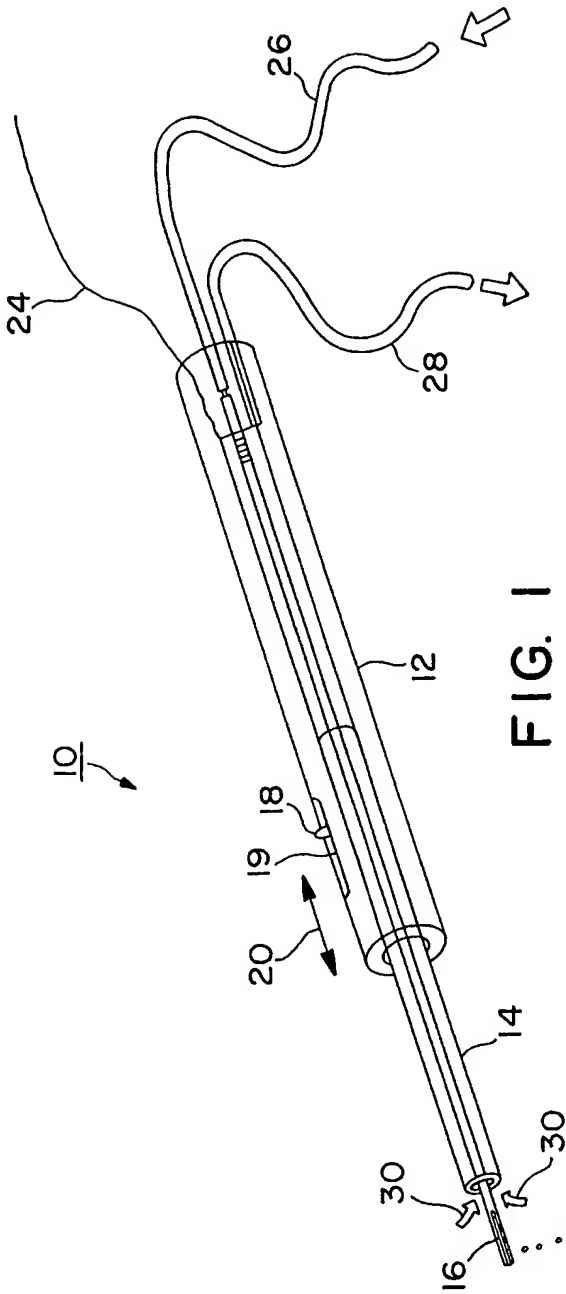
slidable between a fully retracted position wherein a distal end of said electrode extends beyond said distal end of said suction tube, and a fully advanced position wherein said distal end of said electrode is disposed within said suction tube.

5. A method of performing electrocautery, comprising the steps of:

5 (a) applying radio-frequency energy to an electrocautery site via a hollow, conductive electrode;

(b) simultaneously with step (a), infusing said electrocautery site with a conductive liquid expelled from said electrode.

10 6. A method in accordance with claim 5, further comprising the step of aspirating smoke and fluid the electrocautery site with a suction tube partially surrounding said electrode.



INTERNATIONAL SEARCH REPORT

Inter. Application No
PCT/US 96/15796

A. CLASSIFICATION OF SUBJECT MATTER IPC 6 A61B18/14 A61M1/00		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 6 A61B A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 326 529 A (DOSS JAMES D ET AL) 27 April 1982 see abstract; figures 1-5 see column 3, line 13 - column 4, line 10 ---	1-4
Y	US 5 472 441 A (EDWARDS STUART D ET AL) 5 December 1995 see abstract; figure 1 see column 7, line 1 - line 55 ---	1-4
A	US 1 735 271 A (SUTTEN H. GROFF) 12 November 1929 see page 1, line 44 - page 2, line 10; figure 1 --- -/--	2
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 2 June 1997		Date of mailing of the international search report 12.06.97
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016		Authorized officer Zeinstra, H

INTERNATIONAL SEARCH REPORT

Inter: nal Application No
PCT/US 96/15796

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 90 03152 A (CONSIDINE JOHN ;COLIN JOHN BUNCE (GB)) 5 April 1990 see abstract; figures 6-9 see page 9, line 14 - page 12, line 8 ---	1,3,4
A	US 5 167 659 A (OHTOMO NAOKI ET AL) 1 December 1992 see abstract; figures 1-3 see column 1, line 63 - column 2, line 37 see column 3, line 11 - line 68 ---	1
A	US 5 401 272 A (PERKINS RODNEY C) 28 March 1995 see abstract; figure 1A see column 2, line 59 - column 3, line 35 -----	1

INTERNATIONAL SEARCH REPORT

(1): International application No.

PCT/US 96/ 15796

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 5,6
because they relate to subject matter not required to be searched by this Authority, namely:
PCT Rule 39.1 (iv)
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 96/15796

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